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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,644	01/08/2002	Jacques F. Banchereau	112917-143	7691

28089 7590 04/28/2005

WILMER CUTLER PICKERING HALE AND DORR LLP
399 PARK AVENUE
NEW YORK, NY 10022

EXAMINER
CHANDRA, GYAN

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,644	BANCHEREAU ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 10042644
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

After a discussion with Jane Love on 05 April 2005 (see attached interview summary) and subsequent review of the instant claims, the Examiner has determined that additional claim groups are required in the restriction. Therefore, the Restriction requirement of 18 March 2005 is hereby vacated. For Applicant's records, please use the mail date of the current office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims1-27, drawn to a method of treating an autoimmune disease comprising (a) at least one interferon antagonist and (b) one Flt3 ligand antagonist, classified in class 424, subclass 130.1.

II. Claims 28-39, drawn to a therapeutic composition, classified in class 512, subclass 2.

III. Claims 43-46, drawn to an in vitro assay for determining a subject's risk for developing an autoimmune disease, classified in class 435, subclass 4.

IV. Claims 47-52, drawn to a kit for determining a subject's risk for an autoimmune disease, classified in class 435, subclass 810.

V. Claims 53-68, drawn to a method of treating an autoimmune disease in a subject comprising administering an interferon antagonist, classified in class 424, subclass 85.4.

VI. Claims 69-77, drawn to a method of treating an autoimmune disease in a subject comprising administering a Flt3L antagonist wherein the

antagonist is an antibody that specifically binds Flt3L or an antigen, classified in class 424, subclass 130.1.

VII. Claims 69-77, drawn to a method of treating an autoimmune disease in a subject comprising administering a Flt3L antagonist wherein the antagonist wherein the antagonist is an organic molecule, classified in class 514, subclass 1.

VIII. Claims 69-77, drawn to a method of treating an autoimmune disease in a subject comprising administering a Flt3L antagonist wherein the antagonist wherein the antagonist is a nucleic acid, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and IV are patentably distinct inventions for the following reasons. Groups II and IV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The therapeutic composition of Group II comprises (a) an interferon antagonist that reduces activity of type I interferon and (b) a Flt3L ligand antagonist that reduces activity of Flt3L. Meanwhile, the kit of Group IV comprises a composition that binds to Flt3L and a composition that binds IFN-α.

Furthermore, searching the inventions of groups II and IV together would impose a serious search burden. In the instant case, the search of the composition of Group II and the Kit of Group IV are not coextensive. The inventions of Groups II and IV have a

separate status in the art as shown by their different classifications and separate search requirements.

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case composition of Group II can be used to treat other immune related diseases or to prepare antibodies of cell based assays.

Searching the inventions II and I together would impose undue search burden. The inventions of II and I have a separate status in the art as shown by their different classifications. Moreover, the search for a composition and the methods of treating an autoimmune disease are not coextensive.

Inventions IV and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case composition of the kit of Group IV can be used in cell culture assays or protein purification techniques.

Searching the inventions IV and III together would impose undue search burden. The inventions of III and IV have a separate status in the art as shown by their different

classifications. Moreover, the search for a kit of Group IV and the in vitro method assay for determining an autoimmune disease are not coextensive.

Inventions II and III, V/ VI/ VII/VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated. For example, the claimed methods III, V/ VI/ VII/VIII do not recite the use therapeutic composition from Group II.

Inventions IV and I, V/ VI/ VII/VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).). In the instant case the different inventions are unrelated. For example, the claimed methods I, V/ VI/ VII/VIII do not recite the use of a kit from Group IV.

Inventions I, III, V-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of treating an autoimmune disease comprising (a) at least one interferon antagonist and (b) one Flt3 ligand antagonist (Group I), the method of an in vitro assay for determining a subject's risk for developing an autoimmune disease (Group III), the method of treating an autoimmune disease in a subject comprising administering an interferon antagonist (Group V), the method of treating an autoimmune disease in a

subject comprising administering an antibody that binds Flt3L or an antigen (Group VI), the method of treating an autoimmune disease in a subject comprising administering an organic molecule (Group VII), and the method of treating an autoimmune disease in a subject comprising administering a nucleic acid (Group VIII) are unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Each invention performs this function using a functionally divergent material.

Furthermore, the inventions of Groups I, III, V-VIII require separate, distinct and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups I, III, V-VIII together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and separate search requirements, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species of the claimed invention:

A. An autoimmune disease is selected from:

i) acquired immune deficiency syndrome (AIDS)

ii) ankylosing spondylitis

iii) arthritis

iv) aplastic anemia

v) Behcet's disease

vi) diabetes

vii) graft-versus-host disease

viii) Graves' disease

ix) hemolytic anemia

x) hypogammaglobulinemia

xi) hyper IgE syndrome

xii) idiopathic thrombocytopenia purpura (ITP)

xiii) multiple sclerosis (MS)

xiv) Myasthenia gravis

xv) psoriasis

xvi) lupus

xvii) systemic lupus erythematosus (SLE)

xviii) drug-induced lupus

xix) diabetes melitus

xx) Type I diabetes

xxi) Type II diabetes

xxii) juvenile on-set diabetes

xxiii) rheumatoid arthritis

xxiv) juvenile rheumatoid arthritis

xxv) psoriatic arthritis

Claims 1, 53 and 69 are generic to a plurality of disclosed patentably distinct species comprising an autoimmune disease. Each disease is considered to constitute a patentably distinct species because they have separate disease etiology, population sample makeup and require separate searches, for example NPL. Search of more than a single species would constitute an undue burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 53 and 69 are the examples of a generic claim.

B. An interferon antagonist is:

xxvi) an antibody

xxxvii) an antigen-binding fragment of an antibody

xxxviii) a peptide

xxix) a peptidomimetic

xxx) a nucleic acid encoding a peptide

xxxi) an organic molecule

xxxii) TNF

xxxiii) a TNF agonist

xxxiv) a TNF receptor agonist

xxxv) soluble IFN-α

Claims 1 and 53 are generic to a plurality of disclosed patentably distinct species comprising an interferon antagonist. Each interferon antagonist is considered to

constitute a patentably distinct species because they have separate structure and function and require separate searches, for example NPL. Search of more than a single species would constitute an undue burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1 and 53 are the examples of a generic claim.

C. A Flt3L antagonist is:

xxxvi) an antibody

xxxvii) an antigen-binding fragment of an antibody

xxxxviii) a peptide

xxxix) a peptidomimetic

xxxx) a nucleic acid encoding a peptide

xxxxi) an organic molecule

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising a Flt3L antagonist. Each Flt3L antagonist is considered to constitute a patentably distinct species because they have separate structure and function and require separate searches, for example NPL. Search of more than a single species would constitute an undue burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1 is the example of a generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

If Applicant selects Group I, one species from the autoimmune disease group, one species from the interferon antagonist group and one species from the Flt3L antagonist must be chosen to be considered fully responsive. If Applicant selects Group II, one species from the interferon antagonist group and one species from the Flt3L antagonist must be chosen to be considered fully responsive. If Applicant selects Group V, one species from the autoimmune disease group and one species from the interferon antagonist group must also be chosen to be considered fully responsive.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gyan Chandra
AU 1646
20 April 2005

Bridget E. Bunner
patent examiner